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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/548,403

07/27/2006

Marie Bendix Hansen

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EXAMINER

KIM, ALEXANDER D

ART UNIT

PAPER NUMBER

1656

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DELIVERY MODE

03/31/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/548,403</p>	<p>Applicant(s) HANSEN ET AL.</p>	
	<p>Examiner ALEXANDER D. KIM</p>	<p>Art Unit 1656</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 March 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-15.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Rebecca E. Prouty/
Primary Examiner, Art Unit 1652

Continuation of 11. does NOT place the application in condition for allowance because: Applicants have responded after the Final rejection, mailed on 10/29/2008, is acknowledged. The said response does not have any claim amendment from the previous claims before Final Office Action.

Applicants' arguments in the response filed on 03/20/2009 have been fully considered. However, applicant's arguments are not found persuasive to overcome the outstanding rejection(s) as set forth in the Final Office action mailed on 10/29/2008 for the reasons of record stated herein.

Applicants argue that the Examiner's assertion not having support for "a linear flow rate of at least 1500 cm/hour" is factually incorrect because one skilled in the art reviewing the specification would recognize instantly that the phrase "1.500 cm/hour" contains a punctuation error and one skilled in the art would recognize instantly that reciting a flow rate of 1.5 cm/hour is unrealistic in this context. Applicants also argue that instant specification reciting "one major advantage of the invention relates to the utility of high flow rates, rather than the conventional ones which amount to about 200 cm/hour" (see US2007/0092960, §0061) supports the idea that one skilled in the art would recognize that a linear flow rate of at least 1.5 cm/hour is unrealistic (see page 2, Remark filed on 3/20/2009). Applicants also argue that the Example 1 shows 3459 l was processed in 3.26 hours using 30 cm diameter and a skilled person would recognize that the flow rate in the examples equates to 1500 cm/hour and not 1.500 cm/hour (see top of page 3, Remarks filed on 3/20/2009).

The Examiner disagrees with the Applicants' argument since Applicants are not limited to claim only what is shown in the specification or examples. Applicants were entitled to claim any ranges of flow rate as long as it is supported by the original disclosure in the application. The recitation of "at least 1.5 cm/hour" is not an unrealistic range as taught by the reference disclosed in the previous 102(b) rejection (see page 5 of the Non-Final office action mailed out on 3/10/2008). Applicants argue the recitation "3000 to 7000 cm/hour" in the §0061 cannot lie between a range of 1.8 and 10 cm/hour or 2 to 10 cm/hour; unless they are read as "1800 to 10000" cm/hour or "2000 to 10000 cm/hour"; thus, 1.5 cm/hour must be read "1500 to 12000 cm/hour". However, in view of the reasoning above, and as written, the §0061 recites three different preferable ranges and there are no restrictions in terms of reciting such three distinct ranges within a paragraph. Furthermore, there is no single recitation of flow rate of at least 1500 cm/hour within the application; wherein the flow rate of 1.500 cm/hour is recited about 9 times in the instant application.

Applicants argue that 1.5 cm/hour is inoperable in the field of expanded bed technology because a chromatographic bed can not expand at such extremely slow flow rates. However, as written, the flow rate has no relationship to whether the column bed can be expanded or not; claim does not require the chromatographic bed is expanded by the fast flow rate, but only recites applying a biomolecule to an expanded bed adsorption that is already expanded and is operated.

Applicants argue that objection to the specification should be withdrawn for the same arguments above (see middle of page 3, Remarks filed on 3/20/2009). However, for the same reasons stated above by the Examiner, the objection to the specification is maintained.

Applicants argue that there is no combination of the cited material yields an isolation process employing high temperature (at least 40°C) and high flow rate at least 1500 cm/hour (see top of page 4, Remarks filed on 3/20/2009); and the Examiner failed to establish a motivation for combining the cited references as the conditions applicable to packed bed chromatography are not comparable to those for expanded bed chromatography and Ahern's comment would not have led an artisan to modify Kawakami's method to reach the claimed processes.

However, as noted in the previous final office action "Kawakami et al. specifically recites "In the present invention, the contact of the sulfuric ester with raw milk containing lactoferrin is conducted at a temperature of 50°C" (see §2, lines 40-42), which involves step of heating the milk and the column to at least 50°C" and the recited flow rate would be met if a flow rate is increased in view of motivation provided in the office action; that is "faster flow rates lead to quicker separations with better resolution" and that "liquid chromatography performed under pressure is a powerful analytical and preparative tool for chemists and life scientists"; thus, support a prima facie case of obviousness.

For the reasons above, the instant claims are not in condition for allowance.